SEP 2 6 2002

K010216

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. Submitter:

LAP of America, L.C.
1755 Avenida Del Sol
Boca Raton, Fl 33432

Contact: Pieter van Arkel
Designated Agent
Phone: (561) 416 9250
Fax: (561) 416 9263

Prepared: January 22, 2001

2. Common or Usual Name: Laser Marking System

Proprietary Name: LAP Dorado CT-4 CT Simulation Isocenter and Field Marking System

Classification Name: Radiation Therapy Simulation System
21 CFR § 892.5840 Class II.
Product Code: RA 90 KPQ

Manufactured By: LAP Laser Applikationen, GmbH
Zeppelin Strasze23
D-21337, Lüneburg, Germany

Distributed By: LAP of America, L.C.
1755 Avenida Del Sol
Boca Raton, Fl 33432

K010216

3. **Predicate Device:** MKS Beam Outline Projector K 921876

2 4. Device Description:

The LAP Dorado CT-4 is a moving laser light system that has two moving lasers on linear rails that are installed on the sidewalls of the CT room. The moving lasers are enclosed in a housing that also contains a stationary laser. Another housing containing three linear rails, each having a moving laser, is mounted on the ceiling of the CT room. The lasers can be moved with a hand held keypad (terminal). The system is usually operated under computer control via a RS485 interface to the LAP PC. Prescribed laser movement data is created by a remote host 3D radiation therapy planning or virtual simulation computers and transmitted to the LAP PC via an Ethernet connection.

5. Indication for Use:

LAP Dorado CT-4 CT Simulation Isocenter and Field Marking System is a computerized laser positioning device used for projecting and marking of radiation treatment beam isocenter and outline geometry of the treatment field on the skin of the patient in CT radiation therapy simulation.

6. Comparison with Predicate Device:

It is the opinion of LAP of America that the LAP Dorado CT-4 CT Simulation Isocenter and Field Marking System, although mechanically different, is substantially equivalent to the MKS Beam Outline Projector. The safety and effectiveness of the LAP Dorado CT-4 Patient CT Simulation Isocenter and Field Marking System is substantially equivalent to the predicate device and it does not represent any new potential safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2002

Mr. Pieter van Arkel
LAP of America Laser Applications L.C.
1755 Avenida Del Sol
BOCA RATON FL 33432

Re: K010216
Trade/Device Name: LAP Dorado CT-4 CT Simulation Isocenter and Field Marking System
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: June 25, 2002
Received: June 28, 2002

Dear Mr. van Arkel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Ver/3-4/24/96

Applicant: LAP of America, L.C.

510(K) Number (if known): K010216

Device Name: LAP Dorado CT-4 CT Simulation Isocenter and Field Marking System

Indications for Use:

LAP Dorado CT-4 Patient CT Simulation Isocenter and Field Marking System is a computerized laser-positioning device used for projecting and marking of radiation treatment beam isocenter and outline geometry of the treatment field on the skin of the patient in CT radiation therapy simulation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device-Evaluation (ODE)

(Per 21 CFR 801-109

Prescription Use ✓

David R. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010216